

7.4,  $p = 0.0065$ ) among groups Vioxx, Cox2-Vioxx and Others in the adverse events rates of 5.84%, 5.00% and 3.83% respectively. Further Logistic regression analysis revealed that Vioxx and Cox2-Vioxx patients experienced higher events rates (group Vioxx vs. Others: OR = 1.218, 95%CI = 0.905–1.640; group Cox2-Vioxx vs. Others OR = 1.13, 95%CI = 0.834–1.532) with influencing factors adjusted, gender (male OR = 1.555, 95%CI = 1.190–2.031), age (OR = 1.080, 95%CI = 1.063–1.097) and comorbidities. **CONCLUSIONS:** The study demonstrated that Vioxx before withdrawn from market had highest heart attack/stroke events as compared to other Cox2 drugs or drug class. The other Cox2 drugs, Celebrex and Bextra, had higher adverse events than other painkiller classes such as NSAIDs. The follow up study with extended data is expected to confirm the finding.

#### ARTHRITIS—Cost Studies

##### PAR4

#### COST-EFFECTIVENESS ANALYSIS OF RITUXIMAB AS A NEW THERAPEUTIC OPTION FOR RHEUMATOID ARTHRITIS IN THE UK

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**OBJECTIVES:** Rituximab (RTX; MabThera), a unique B-cell therapy, is a new option for rheumatoid arthritis (RA) patients who respond inadequately to anti-TNF therapies. This analysis evaluated the cost-effectiveness of introducing RTX from the perspective of the UK NHS. **METHODS:** The model simulated, over a patient's expected lifetime, the real-life treatment sequence for 10,000 RA patients who respond inadequately to one anti-TNF therapy. Baseline characteristics were aligned with the REFLEX study. Clinical outcomes were based upon ACR response rates (adjusted for different study populations) and complemented with observational data. The model estimated the incremental cost per quality-adjusted life-year (QALY) of a typical treatment sequence containing RTX compared to the same treatment sequence without RTX. Average time-on-treatment for biological agents was up to 4.25 years. QALYs were mapped from a disease severity measure (HAQ score). All direct NHS costs were included in the model, as well as those related to disease progression and palliative care. Costs and benefits were discounted at 3.5%. **RESULTS:** The annual average drug cost for each drug in the model was BRP5834 for RTX + MTX (infusion of 2 × 1 gram every 9 months), BRP10,138 for adalimumab, BRP10,279 for etanercept, and BRP8542 for infliximab. The model estimated that when added to an existing treatment sequence, RTX would lead to a gain of 0.526 QALYs at an additional cost of BRP7417 per patient. The incremental cost-effectiveness ratio (ICER) of RTX was consequently BRP14,122. When RTX replaced adalimumab as a second-line biologic DMARD, RTX + MTX was associated with a cost-saving of BRP13,000 over a patient's lifetime. **CONCLUSIONS:** RTX as a treatment option for RA patients who fail to respond to anti-TNF therapy is a cost effective treatment option from the perspective of the UK NHS. The resulting cost effectiveness ratio falls well below commonly accepted thresholds within the UK.

#### COST-EFFECTIVENESS OF RITUXIMAB AS A NEW TREATMENT MODALITY FOR RHEUMATOID ARTHRITIS IN GERMANY

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**OBJECTIVES:** Rituximab (RTX; MabThera), a unique selective B-cell therapy, represents a new option for patients with rheumatoid arthritis (RA) who have responded inadequately to anti-TNF therapies. We analysed the cost-effectiveness of RTX from a German societal perspective. **METHODS:** We developed a model using published ACR response rates for RTX and current treatment choices (adjusted for study population differences), plus available observational data, German registry resource-utilisation data and baseline patient characteristics from the REFLEX study. We modelled real-life treatment for 10,000 RA patients who had responded inadequately to one anti-TNF therapy over the patient's lifetime, assuming an average treatment duration for biological therapy (in combination with methotrexate) of up to 4.25 years. QALYs were mapped from a disease severity measure (HAQ score). Relevant costs (2004–5 Euros [€]) included those related to drug (including administration and monitoring) and indirect costs through reduced productivity. Costs and benefits were discounted at 3.5% per year. We assessed either adding RTX or using it instead of adalimumab. **RESULTS:** Annual average drug therapy costs were €10,208 for RTX + MTX, €22,574 for adalimumab, €22,630 for etanercept, and €13,484 for infliximab. RTX as an additional treatment gave an additional 0.531 QALYs at an incremental total direct medical cost of €16,527 over the patient's lifetime. With an incremental QALY of 0.665 this would result in an incremental direct medical cost of €24,844 per QALY. The corresponding ICERs were €25,985 and €17,058 per QALY gained. Using RTX as an alternative to adalimumab would produce a small incremental QALY gain, together with lifetime cost-savings of €23,143. **CONCLUSIONS:** In Germany, the incremental cost of adding RTX to options for RA-patients who respond inadequately to anti-TNF therapy is favourable using commonly accepted cost-effectiveness thresholds. As a replacement for a currently used drug in second-line biologic DMARD, RTX could lower average annual treatment costs.

##### PAR6

#### MODELING THE IMPACT OF PATIENT AND CLINICAL HETEROGENEITIES ON THE COST-EFFECTIVENESS OF SELECTIVE COX-2 INHIBITORS SUCH AS LUMIRACOXIB AND CONVENTIONAL NSAIDS IN PATIENTS WITH OSTEOARTHRITIS

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**OBJECTIVES:** To explore influences of patient and clinical characteristics on the cost-effectiveness of selective COX-2 inhibitors and traditional NSAIDs in patients with osteoarthritis. **METHODS:** A published cost-effectiveness model (Arthritis Rheum 2003;49:283–92) was modified to incorporate important clinical characteristics that can influence the risk of gastrointestinal (GI) complications such as age, gender, history of GI bleed, and low-dose aspirin intake. The modified model used data from a large clinical trial (TARGET) to estimate base GI